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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,009	05/30/2001	Hisashi Kashima	JP920000069US1	8419

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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,009	KASHIMA ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,8-12 and 15-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,8-12 and 15-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 4/13/04, are acknowledged. Amended claims 5, 8, 11-12, 15, 26-27 and new claims 28-30 are acknowledged.

Applicant's arguments, filed 4/13/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The drawings, filed 4/13/04, have been approved by the Examiner.

Claims 5, 8-12, and 15-30 are herein under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of claims 5, 8-12, 15, and 17-27 is maintained and newly applied to new claims 29-30 under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter.

This rejection is maintained (claims 5, 8-12, 15, and 17-27), necessitated by amendment (claims 29-30), and reiterated for reasons of record.

Claims 5, 8-12, 15, 17-27, and 29-30 do not sufficiently distinguish over nucleic acids and cells as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. It is acknowledged that insertion of special and non-natural sequences is described in the specification, but not particularly in these claims. Thus, one interpretation of the claims is that they are inclusive of DNAs wherein a watermark sequence is merely recognized in a naturally occurring DNA. In the absence of the hands of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980).

Applicants state that the nucleotide sequence added to a portion of DNA is not just any old nucleotide sequence, but instead includes "source identification information" for identifying a source of the genetic information in the gene portion and that this implies some human intervention. This statement is found unpersuasive as any fragment of DNA has the ability to identify a DNA sequence due to the makeup of nucleotides in the sequence that one skilled in the art can identify via sequence analysis. A fragment of DNA in nature can be used for such identification with no human involved. Applicants state the source identification information is "for identifying" a source of genetic information in the gene portion which implies some human intervention. This is found unpersuasive as one skilled in the art is aware that conserved regions of any DNA with specific nucleotide reads may be used as fragments for identification, and these fragments are not necessarily tampered with by the hands of man. Applicants state claim 5 defines DNA having a nucleotide sequence that is embedded in a portion of the DNA which implies some human intervention. This is found unpersuasive as introns and jumping genes are

embedded in DNA and natural occurrences are responsible for their embedded nature. The online Merriam Webster dictionary defines the term "embed" as to enclose closely in or to surround closely which does not imply that human intervention took place. Applicants state DNA to which a nucleotide sequence which includes information for identifying a source of genetic information has been embedded is naturally-occurring is contrary to common sense and is obviously incorrect. This statement is found unpersuasive and confusing as there are several instances in the natural world (some of which are documented above) that illustrate a naturally occurring embedding of a nucleotide sequence in DNA without the hands of man.

Claims Rejected Under 35 U.S.C. § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 5, 8-12, and 15-27 is maintained under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

These rejections are maintained and reiterated for reasons of record.

Claims 5, 12, and 15 recite the phrases "a portion, other than said gene portion, including no genetic information", "said portion including no genetic information", and "a second portion which is devoid of genetic information" which are vague and indefinite. It is unclear how a portion of DNA can be considered not to have genetic information when it is well known in the

art that DNA is made up of nucleotides which are considered to be genetic information. Clarification of this issue, via clearer claim wording, is requested. Claims 16-27 are also rejected due to their direct or indirect dependency from claim 15. Applicants cite a section of the application that states "DNA consists of a gene portion [...] and a portion wherein genetic information is not included" (page 13, lines 3-6). Applicants conclude that a portion of DNA having no genetic information is a portion other than a protein code sequence and its transcription control information. This is found unpersuasive as Applicants' use of the sentence on page 13 does not specifically define "genetic information". Therefore, Applicants' assertion is an interpretation of the phrase "no genetic information" that is not specifically defined. In the absence of such specific definition, the Examiner is required to interpret terms as broadly and reasonably possible which includes genetic information to be in all DNA by the mere presence of nucleotides which themselves are broadly and reasonably interpreted to be genetic information.

Claims 5, 8, 11, 12, and 15 recite the phrase "so as not to affect transmission of said genetic information" which is vague and indefinite. It is unclear if the transmission is directed to passing genetic information to other cells or organisms, passing information via transcription and translation, or passing information from one physical location to another. Clarification of this issue via clearer claim wording is requested. Claims 9-10 and 16-27 are also rejected due to their direct or indirect dependency from claims 8 and 15. Applicants merely state this phrase is inherently clear and do not provide any evidence to suggest this rejection is improper. Therefore, this rejection is maintained.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 5, 8-12, and 15-27 is maintained and newly applied to new claims 28-30 under 35 U.S.C. 102(b) as being anticipated by Dollinger (P/N 5,451,505).

These rejections are maintained (claims 5, 8-12, and 15-27), necessitated by amendment (new claims 28-30), and reiterated for reasons of record.

Dollinger discloses nucleic acids which are used as taggants that allows for subsequent identification of a substance, product identity (col. 1, lines 11-16 and 25-27) which represent watermark sequences. Dollinger discloses a taggant as a nucleic acid that comprises a specific nucleotide sequence or composition (col. 2, lines 59-62). The term "genetic information" used in the claims lacks clarity, but the nucleotide sequence can be considered to be genetic information in the sense that it contains nucleotides. Dollinger discloses any substance may be used for tagging by treating the substance with a nucleic acid taggant (col. 1, lines 50-54). Dollinger discloses nucleic acids that are covalently bound to the tagged material (including the taggant) (col. 2, lines 15-18) which is reasonably interpreted to be a gene portion and other portion (taggant), as stated in instant claim 5. Dollinger discloses tagging any substance with a nucleic acid taggant so that the nucleic acid attaches to the material (col. 1, lines 50-54). Dollinger

discloses the nucleic acid taggant comprises a specific nucleotide sequence or a composition of specific nucleotides to facilitate tracing or determining the origin or source of a material (col. 1, lines 54-60 and col. 3, lines 7-8). Dollinger discloses the nucleic acids can be either naturally occurring or synthetically derived (col. 2, lines 6-7), as stated in instant claims 16 and 28, as well as not being naturally generated through gene mutation (as stated in instant claim 23). Dollinger discloses the taggants are typically non-biologically functioning and are not part of a functional nucleic acid sequence operating in a living cell (col. 2, lines 62-65) which is reasonably interpreted to mean the taggant sequence does not affect transmission of biologically functional genetic information (as stated in instant claims 5, 8, 12, 15, and 29). Dollinger discloses using combinations of sequences and varying levels of specific sequences to identify the product, product's origin, the lot or batch, or an identifier for a unit of commerce (col. 3, lines 22-28) as well as using a sequence with multiple regions of specificity (col. 5, lines 9-11) which is reasonably interpreted to encompass multiple patterns at predetermined locations, as stated in instant claims 9, 10, 18, 19, and 20. The instant specification, page 1, second paragraph, defines "value-added genes" as having properties or values rated and levels assigned and creating added value to the gene. Dollinger discloses tracking animals and plants (gene bearing organisms) (col. 1, lines 17-19) which is reasonably interpreted to be determining product identity for cultivation or breeding purposes including value-added genes, as stated in instant claim 17. Dollinger discloses amplifying the sequence prior to detection via polymerase chain technology (col. 2, lines 3-5) which is reasonably interpreted to mean being copy tolerant, as stated in claim 21. Dollinger discloses the nucleic acids may be bound to solid support (devoid of genetic information and predetermined location) that is then mixed with the material being tagged (col.

2, lines 23-26), as stated in instant claim 15. Dollinger discloses tagging methods involve detection and PCR technology where the nucleic acid must form duplexes with primers (complementary sequence) (col. 3, lines 41-47) and using hybridization techniques (col. 6, lines 3-20), as stated in claim 25. As it is unclear if instant claim 24 requires either a restriction enzyme identification or a promoter or both, Dollinger discloses promoters can be incorporated in the primers (col. 5, lines 47-51), as stated in claim 24. Dollinger discloses use of a taggant of a sequence complementary to the DQα allele (gene) (col. 6, lines 55-56).

Thus, Dollinger anticipates the instant invention.

Applicants state that the Dollinger reference does not teach or suggest "a nucleotide sequence which is embedded in said portion including no genetic information..." as recited in claims 5 and 12. This is found unpersuasive as Dollinger does disclose these limitations when one skilled in the art broadly and reasonably interprets "embedded" and "genetic information" which are discussed in detail in the 35 USC 101 and 35 USC 112, second paragraph, rejections, supra. Applicants further state that conventional DNA does not include any information therein to determine the source of a value-added gene. This is found unpersuasive as DNA is made up of nucleotides that store information depending on their order. Dollinger uses nucleotides as taggants clearly read on a nucleotide sequence comprising source identification information in the instant invention. Applicants also state since DNA having such a value-added gene is easily copied, it is difficult to apply technical restrictions to the copying, by third parties, of such value-added genes. This is found unpersuasive as there is no mention of this last statement in the claims. Applicants state Dollinger's use of a material to be tagged and traced by tagging the material with a nucleic acid taggant is different from the instant invention which includes source

identification information for identifying a source of genetic information in the gene portion. This is found unpersuasive because a taggant does serve as a valid way of identifying source a source of genetic information. The specific order of nucleotides is a structural representation necessary for identification to occur. Applicants state that using a nucleic acid to trace a material is completely different from using an embedded nucleotide sequence that does not identify a source of genetic information. This is found unpersuasive as broad interpretations of the instant claims present definite overlap between the instant invention and Dollinger's invention. While the Applicants intended invention expressed in their arguments is not exactly Dollinger's invention, the instant rejected claims are broadly and reasonably interpreted to include Dollinger's invention. Therefore, the 35 USC 102 rejection is maintained for claims 5, 8-12, and 15-27 and newly applied to new claims 28-30.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

May 6, 2004